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10/806,487

03/23/2004

Greg Marik

31132.196

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46333

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01/26/2006

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EXAMINER

AMARELD JR, ROBERT W

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |   |                                     |  |
|------------------------------|---|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/806,487      | <b>Applicant(s)</b><br>MARIK ET AL. |  |
|                              | <b>Examiner</b><br>Robert W. Amareld, Jr. | <b>Art Unit</b><br>3738             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/29/05, 8/29/04, 7/23/04, 3/11/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the depressions in the first and second surfaces as per claim 12 must be shown in the manner in which they are claimed, or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20, 24-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/806,961. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are essentially identical in scope, with the only notable difference being the preamble of each claim (intervertebral implant vs. joint prosthesis), which carries no patentable weight.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification and diagrams support movement in the direction of the two axes (66 and 62), however movement in the direction of a third axis (44) is not explained or elaborated on. The third and only available axis that is orthogonal to the first and second axes 66 & 62 is the axis of 44, which is in the up and down direction. It is not clear as to how it is possible for the two surfaces of this device to translate along each other and move in an up and down direction, while the device is fully capable of tilting, where either edge might move in an up and down direction, it seems impossible for the device to translate in a up and down direction as claimed. The examiner will interpret any device which has a first member which is capable of moving in the up and down direction, even by separation from the other members of the device as meeting the claimed subject matter.

Art Unit: 3738

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the central element. It appears that the applicant is attempting to claim 1<sup>st</sup> and 2<sup>nd</sup> surface depressions as per Figures 26-30, however these depressions cannot be present without the central element and negating claim one, from which it depends, which would require the depressions to be on curves that that are within one another and translate.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. If the two claimed surfaces as per the independent claim #1, which claim 20 depends from are both concave, the two surfaces would oppose each other, but it is unclear as to how the first and second surface can be concave and still meet the requirements of claim 1, where the second curve is positioned within the first curve and curves translate along one another.

Art Unit: 3738

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: It is unclear how the conformity between the first and second curved surface may be increased. There is no structural limitation or specification support describing the means by which the conformity increases. The examiner will interpret any two surfaces that conform and translate along their perspective surfaces and make contact with another area of the surface during the translation as increasing in conformity

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8, 9, 11, 13-15, 17-19, 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shima (US Pat# 5534029). Shima discloses a joint

Art Unit: 3738

prostheses with a first and second bone engaging member (5 & 4) that have first and second curved surfaces (10 & 6) and the second curve is placed within the first curve (Figure 1) and is fully capable of biasing alignment toward through first and second bone portions (column 4, lines 40-45), where alignment comprises alignment of the center points of both portions (5 & 4). Both curves have a constant radius and demonstrated in Figure 1, where the first constant radius is larger than the second constant radius, the second curve comprising a semi-spherical protrusion, which also demonstrates that the 1st curve is wider than the second, figure 1 also shows the first curve being superior to the first. The center member (20) may be disposed between the two surfaces (Figure 5) and is capable of articulation when the 1<sup>st</sup> and 2<sup>nd</sup> members translate relative to each other. The device contains surfaces (12 & 8) as a restraint mechanism for restricting motion along a second axis (column 2, 10-27), where the device may be taken apart where the upper device portion(5) may be moved in an upward, third direction orthogonal to the other two directions. The spherical joint like interaction of the parts (5 & 4) is capable of biasing the device to a neutral position, which would be the natural centered position of the two devices relative to each other. The first curve is concave and the second is convex (Column 4, lines 9-15). The conformity of the first and second surfaces may increase through translation when the device is translated to the point where the stopping surfaces (8 & 12) contact and conform to one another. Furthermore, the device is fully capable of being used for a shoulder, knee or hip joint. Please note the intended



Art Unit: 3738

use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Claims 1,6-9, 17, 19 & 20 & 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon (US Pat#6146421). Gordon discloses a joint prostheses with a first and second bone engaging member (80 & 44) that have first and second curved surfaces (54 & 60) and the second curve is placed within the first curve (Figure 7), where the first curve is wider than the second and is fully capable of biasing alignment toward through first and second bone portions, where alignment comprises alignment of the center points of both portions. The cup shaped portion (54) is curved into a cup shape and as the angled wall moves outward, the radius increases, where the curve is curved in the circular direction and flat in the direction of increasing radius, also containing the flat bottom surface. The device also includes the center member (194) which articulates between the 1<sup>st</sup> and second surface (column 6, lines48-65). Both the first and second curve are concave, cup shape 54 is concave as well as center fitting portion 64, while the second surface (60) also has convex portions. The device is capable of being assembled, as shown in Figure 4, where the center member may be engaged into curved cup portion 54 of the 1<sup>st</sup> member, then engaged to the curved portion (64) of the second member, where the second member is within the interior of the first member upon assembly (Figure 7) where the device is disclosed as an intervertebral device, where each surface (80, 44) of each member will engage a first and second bone portion, where the first member is

Art Unit: 3738

translatable and the first and second surfaces are biased toward alignment by their perspective curved structures.

Claims 1,6, 7, 15, 16, 24 & 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishijima (US Pat# 5899941). Nishijima discloses a joint prostheses with a first and second bone engaging member (2 &3) that have first and second curved surfaces (11 &15) and the second curve is placed within the first curve (Figure 1), where the first curve is wider than the second and is fully capable of biasing alignment toward through first and second bone portions, where alignment comprises alignment of the center points of both portions. The first curved surface has a variable radius as demonstrated by its transition from a curved to flat surface as shown in the embodiment of Figure 7 (column 4, lines 63-67; column 5, lines1-2) where these surfaces act as a bias to a neutral position, where when the second curve (11) translates from a first position to a second position (Figures 6A, B), the 1<sup>st</sup> curved portion (15), which has horizontal surface (16) and curves surface (17) will move from the position over the horizontal portion (16) of the first curve (15), which has a lesser conformance to the 2<sup>nd</sup> curve (11), to the curved portion (17) of the first curve, which will have a closer and increased conformance with the second curve, simply by being curved instead of flat. Furthermore, the first curved surface (15) may be comprises by a flat surface portion (15,16- Figure 8A &B), where the second curve (11) may translate unrestrained within the lips (14).

Claims 1, 10 & 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cauthen (US Pat# 5676701). Cauthen discloses a first member (22) and a second member (20) each with a curve (100,101) that is translatable along the other curve where the curved surfaces act as a bias toward alignment. The second curved surface is semi-cylindrical in shape as shown in Figure 8 and 10a. The embodiment of Figure 9 shows both curves with depressions, the second member having a depression opposite the midpoint (105) and the first member having a depression to form the hourglass shape of the base (103)

Claims 1, 10 & 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Khandkar (US Pub# 2004/0133281, Appl# 10/737,101). Khandkar discloses a first member (30) and a second member (32) each with a curve (42,44) that is translatable along the other curve where the curved surfaces act as a bias toward alignment. Both curved surfaces are semi-cylindrical in shape and have depressions. The depressions are shown in the embodiments of Figures 16-18, where each surface is curved (74,72) yet also has the central depression (76, 78)

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berry, US Pat# 5895428 – spinal joint implant; Yuan, US Pat# 5676701 – spinal disc; Krueger, US Pub # 2004/0143332, Appl # 10/699618 – movable disc implant; Tohidi, US Pub # 2003/0208280, Appl # 10/296568- artificial joint; Branemark, US Pat# 5360449 – artificial joint.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

  
**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

Robert W Amareld, Jr.  
Examiner  
Art Unit 3738

